

[107H5646]

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(Original Signature of Member)

108TH CONGRESS
1ST SESSION

H. R. _____

To restore standards to protect the privacy of individually identifiable health information that were weakened by the August 2002 modifications, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. MARKEY introduced the following bill; which was referred to the
Committee on _____

A BILL

To restore standards to protect the privacy of individually identifiable health information that were weakened by the August 2002 modifications, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Stop Taking Our
5 Health Privacy (STOHP) Act of 2003”.



1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) People in the United States are deeply con-
4 cerned about the confidentiality of their health infor-
5 mation. According to a survey conducted by the
6 Princeton Survey Research Associates, 1 in 6 people
7 in the United States has done something out of the
8 ordinary to keep personal health information con-
9 fidential, including withholding information, pro-
10 viding inaccurate information, or, in some cases,
11 avoiding care entirely.

12 (2) Pursuant to the Health Insurance Port-
13 ability and Accountability Act of 1996, commonly re-
14 ferred to as “HIPAA” (Public Law 104-191; 110
15 Stat. 1936 et seq.), the Department of Health and
16 Human Services issued comprehensive medical pri-
17 vacy regulations, which were promulgated in final
18 form in December 2000.

19 (3) These regulations established a sound foun-
20 dation of privacy protections by prohibiting the use
21 or disclosure of an individual’s health information
22 unless specifically authorized by the regulations or
23 by the individual. The regulations also required
24 health care providers such as physicians and health
25 clinics, health plans, and health care clearinghouses,
26 which are responsible for handling transactions such



1 as billing between health plans and providers, to no-
2 tify individuals about privacy practices regarding
3 disclosure of health information. The regulations
4 also provided individuals with the right to access and
5 copy their own health records, and the right to re-
6 quest corrections of their health records, among
7 other provisions.

8 (4) The regulations took effect on April 14,
9 2000, and required health care providers, health
10 plans (other than small health plans), and health
11 care clearinghouses to comply not later than April
12 14, 2003.

13 (5) On August 14, 2002, the Department of
14 Health and Human Services issued modifications to
15 the December 2000 medical privacy rule that signifi-
16 cantly weakened privacy protections.

17 (6) These modifications eliminated the require-
18 ment that health care providers, health plans, and
19 health care clearinghouses obtain patient consent be-
20 fore using or disclosing patient health information
21 for treatment, payment, or health care operations.
22 This change means that patients' medical informa-
23 tion can be used or disclosed without their permis-
24 sion for a wide range of purposes, including business
25 activities that have nothing to do with patient care,



1 such as the sale or merger of a health maintenance
2 organization (HMO). This change also permits the
3 use and disclosure of information in existing medical
4 records even though patients disclosed the informa-
5 tion with the understanding and expectation that it
6 would not be used or disclosed without their consent.
7 The elimination of consent compromises the con-
8 fidentiality that is the heart of physician-patient re-
9 lationships and is indispensable for the delivery of
10 high-quality health care.

11 (7) The August 2002 modifications also under-
12 mined medical privacy protections by expanding the
13 circumstances under which patients' information can
14 be shared without their knowledge or consent to in-
15 clude activities that consumers typically consider
16 marketing. This change permits pharmacies and
17 other providers to use consumers' medical informa-
18 tion without their permission to mail them unsolic-
19 ited drug product recommendations. Furthermore,
20 providers are not required to disclose fees paid to
21 them by drug companies for sending such commu-
22 nications nor provide consumers with the choice to
23 opt out of such future communications.

24 (8) The August 2002 modifications further un-
25 dermined medical privacy protections by changing



1 the section of the rule governing public health. The
2 change allows providers to disclose medical informa-
3 tion without patient permission to entities regulated
4 by the Food and Drug Administration, such as phar-
5 maceutical companies and medical device manufac-
6 turers, for a broad range of purposes including mar-
7 keting campaigns. In contrast, the December 2000
8 rule allowed nonconsensual disclosure of patient
9 health information for a limited list of public health-
10 related activities, such as reporting serious side ef-
11 fects from a prescription drug to the Food and Drug
12 Administration.

13 (9) Reversal of the August 2002 modifications
14 to the medical privacy rule is integral to any effort
15 to ensure privacy protections for consumers' per-
16 sonal health information and preserve access to
17 high-quality health care in the United States.

18 (10) Congress should restore core medical pri-
19 vacy protections of the December 2000 medical pri-
20 vacy rule by—

21 (A) reinstating the patient consent require-
22 ment for treatment, payment, and health care
23 operations, while ensuring that the requirement
24 does not impede important health care activities



1 such as filling pharmaceutical prescriptions and
2 making physician referrals;

3 (B) returning to the December 2000 defi-
4 nition of “marketing” and thus ensuring that
5 activities typically considered “marketing,” such
6 as drug companies paying pharmacies to send
7 product recommendations to patients, fall under
8 the rule’s privacy protections governing mar-
9 keting activities; and

10 (C) eliminating the broad “public health”
11 loophole created by the August 2002 rule.

12 **SEC. 3. PURPOSE.**

13 The purpose of this Act is to restore patient privacy
14 protections essential for high-quality health care that were
15 undermined by the August 2002 modifications of the De-
16 cember 2000 medical privacy rule.

17 **SEC. 4. RESTORATION OF PRIVACY PROTECTIONS.**

18 (a) CONSENT FOR USES OR DISCLOSURES TO CARRY
19 OUT TREATMENT, PAYMENT, OR HEALTH CARE OPER-
20 ATIONS.—

21 (1) IN GENERAL.—The modifications made to
22 section 164.506 of title 45, Code of Federal Regula-
23 tions, by the August 2002 medical privacy rule shall
24 have no force or effect.



1 (2) CLARIFICATION REGARDING INSTANCES
2 WHEN CONSENT IS NOT REQUIRED.— In addition to
3 the circumstances described in the December 2000
4 medical privacy rule, and notwithstanding any provi-
5 sion to the contrary, such section 164.506 shall be
6 construed and applied so as to permit a health care
7 provider to use or disclose an individual's protected
8 health information without obtaining the prior con-
9 sent of the individual in the following circumstances:

10 (A) A health care provider may use or dis-
11 close an individual's protected health informa-
12 tion to fill or dispense a prescription, search for
13 drug interactions related to that prescription,
14 and determine eligibility and obtain authoriza-
15 tion for payment regarding that prescription, if
16 the health care provider obtains written consent
17 from the individual as soon as practicable.

18 (B) A health care provider may use or dis-
19 close an individual's protected health informa-
20 tion to carry out treatment of that individual
21 if—

22 (i) the individual and the health care
23 provider have not had in-person commu-
24 nication regarding such treatment;



1 (ii) obtaining consent would be im-
2 practicable;

3 (iii) the health care provider deter-
4 mines, in the exercise of professional judg-
5 ment, that the individual's consent is clear-
6 ly inferred from the circumstances, such as
7 an order or referral from another health
8 care provider; and

9 (iv) the health care provider obtains
10 written consent from the individual as soon
11 as practicable.

12 (b) MARKETING.—

13 (1) IN GENERAL.—The modifications made by
14 the August 2002 medical privacy rule to the defini-
15 tion of the term “marketing” in section 164.501 of
16 title 45, Code of Federal Regulations, shall have no
17 force or effect.

18 (2) TREATMENT OF CERTAIN COMMUNICA-
19 TIONS.—The exception for oral communications in
20 paragraph (2)(i) of the definition of the term “mar-
21 keting” in section 164.501 of title 45, Code of Fed-
22 eral Regulations, as contained in the December 2000
23 medical privacy rule, shall have no force or effect.

24 (3) AUTHORIZATIONS FOR MARKETING.—Sec-
25 tion 164.508 of title 45, Code of Federal Regula-



1 tions, shall be construed and applied so as to require
2 that, if an authorization is required for a use or dis-
3 closure for marketing, the authorization shall be
4 considered invalid unless it—

5 (A) uses the term “marketing”;

6 (B) states that the purpose of the use or
7 disclosure involved is marketing;

8 (C) describes the specific marketing uses
9 and disclosures authorized, including whether
10 the protected health information involved—

11 (i) may be used for purposes internal
12 to the covered entity;

13 (ii) may be disclosed to, and used by,
14 a business associate of the covered entity;
15 and

16 (iii) may be disclosed to, and used by,
17 any person or entity other than a business
18 associate of the covered entity; and

19 (D) states that the use or disclosure of
20 protected health information for marketing will
21 directly result in remuneration to the covered
22 entity from a third party, in any case in which
23 a covered entity expects, or reasonably should
24 expect, that such remuneration will occur.



1 (c) PUBLIC HEALTH.—The modifications made to
2 section 164.512(b)(1)(iii) of title 45, Code of Federal Reg-
3 ulations, by the August 2002 medical privacy rule shall
4 have no force or effect.

5 **SEC. 5. DEFINITIONS; EFFECTIVE DATE.**

6 (a) IN GENERAL.—For purposes of this Act:

7 (1) DECEMBER 2000 MEDICAL PRIVACY RULE.—
8 The term “December 2000 medical privacy rule”
9 means the final rule on standards for privacy of in-
10 dividually identifiable health information published
11 on December 28, 2000, in the Federal Register (65
12 Fed. Reg. 82462), including the provisions of title
13 45, Code of Federal Regulations, revised or added
14 by such rule.

15 (2) AUGUST 2002 MEDICAL PRIVACY RULE.—
16 The term “August 2002 medical privacy rule”
17 means the final rule, published on August 14, 2002,
18 in the Federal Register (67 Fed. Reg. 53182), that
19 modified the December 2000 medical privacy rule.

20 (b) OTHER TERMS DEFINED.—For purposes of this
21 Act:

22 (1) BUSINESS ASSOCIATE; COVERED ENTITY;
23 HEALTH CARE PROVIDER.—The terms “business as-
24 sociate”, “covered entity”, and “health care pro-
25 vider” shall have the meaning given such terms in



1 section 160.103 of title 45, Code of Federal Regula-
2 tions, as contained in the December 2000 medical
3 privacy rule.

4 (2) DISCLOSURE; INDIVIDUAL, PROTECTED
5 HEALTH INFORMATION; TREATMENT; USE.—The
6 terms “disclosure”, “individual”, “protected health
7 information”, “treatment”, and “use” shall have the
8 meaning given such terms in section 164.501 of title
9 45, Code of Federal Regulations, as contained in the
10 December 2000 medical privacy rule.

11 (c) EFFECTIVE DATE; NO REGULATIONS RE-
12 QUIRED.—This Act shall take effect on the date of the
13 enactment of this Act and does not require the issuance
14 of regulations.

